

Practitioner's Docket No. 1062/D78

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_

for \_\_\_\_\_

Inventor(s)

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Mandro et al.

Application No.: 10/625,792

Group No.: N/A

Filed: July 23, 2003

Examiner: N/A

For: Optical Displacement Sensor for Infusion Devices

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

(Supplemental Information Disclosure Statement--page 1 of 7)

#### CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\*

(When using Express Mail, the Express Mail label number is *mandatory*;

Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

#### MAILING

[x] deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10\*

[ x ] with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. \_\_\_\_\_ (mandatory)

#### TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

  
Signature

Samuel J. Petuchowski

(type or print name of person certifying)

Date: December 15, 2003

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### **List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ JEPO Search Report
  - 7B. ☒ English Language Version of EPO Search Report
8. ☒ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

**NOTE :** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

## **Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mandro et al. Attorney Docket: 1062/D78  
Serial No: 10/625,792 Art Group Unit: N/A  
Date Filed: July 23, 2003 Examiner Name: N/A  
Invention: Optical Displacement Sensor for Infusion Devices

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AG	6,133,578	Oct. 17, 2000	Typpo	250/497.1

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	AH	DE	19643813	April 2, 1998	Schreiber	

Examiner Signature: \_\_\_\_\_

Date Considered: \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

## Section 6. Copies of Listed Information Items Accompanying This Statement

*NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."*

*NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☐ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

## Section 8. Translation(s) of Non-English Language Documents

*NOTE: "If a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in section 1.56(c), a copy of the translation shall accompany the statement." 37 C.F.R. section 1.98(c).*

*NOTE: "The Office does not intend to require translations unless they have been reduced to writing and are actually translations of what is contained in the non-English language information. Applicants should note, however, that most examiners do not have the ability to understand information which is not in English and that the Office will not routinely translate information submitted in a non-English language. The examiner will consider the information insofar as it is understood on its face, e.g., drawings, chemical formulas, English language abstracts, but will not have the information translated unless it appears to be necessary to do so. Applicants are required to aid the examiner by complying with the requirements for a concise explanation in section 1.98(a)(3) for information submitted in a non-English language." Notice of January 9, 1992, 1135 O.G. 13-25, at 21.*

*NOTE: "The examiner will indicate that the non-English language information has been considered in the same manner as consideration is indicated for information submitted in English." Notice of April 20, 1992 (1138 O.G. 37-41, 41).*

- [x] Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:

DE19643813

*(complete the following, if applicable)*

- [ ] No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.
- [x] The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this certification is

*(check each applicable item)*

(a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
*(type name of inventor who is signing)*

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
*(type name of inventor who is signing)*

(c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 37,910

Tel. No.: (617) 443-9292

Customer No.: 002101

01062/00D78 285455.1

  
\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

Samuel J. Petuchowski

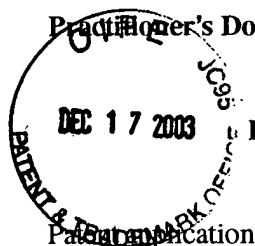
*(type or print name of practitioner)*

Bromberg & Sunstein LLP

125 Summer Street, 11<sup>th</sup> Floor

P.O. Address

Boston, MA 02110



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

OR

In re application of: Mandro et al.

Application No.: 10/625,792

Group No.: N/A

Filed: July 23, 2003

Examiner: N/A

For: Optical Displacement Sensor for Infusion Devices

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. SECTION 1.97(b))**

*NOTE:* " An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as

**CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))**

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date: December 15, 2003

**FACSIMILE**

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature  
Samuel J. Petuchowski

(type or print name of person certifying)



set forth in section 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** The "filing date of a national application" under 37 C.F.R. section 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. section 1.53(b) as "the date on which: (1) A specification containing a description pursuant to section 1.71 and at least one claim pursuant to section 1.75; and (2) any drawing required by section 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by section 1.41." 37 C.F.R. section 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. section 371(c) within the periods set forth in section 1.494 or section 1.495. 35 U.S.C. section 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. section 1.97(b)(2).

### **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

**NOTE:** "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

**NOTE:** "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirement (37 C.F.R. section 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. section 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. section 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

  
\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

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Samuel J. Petuchowski

(type or print name of practitioner)

Bromberg & Sunstein LLP

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Boston, MA 02110

01062/00D78 285516.1



Practitioner's Docket No. 1062/D78

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Mandro et al.

Application No.: 10/625,792

Group No.: N/A

Filed: July 23, 2003

Examiner: N/A

For: Optical Displacement Sensor for Infusion Devices

**Commissioner for Patents**

**P.O. Box 1450**

**Alexandria, VA 22313-1450**

**STATEMENT FOR SUPPLEMENTAL INFORMATION DISCLOSURE UNDER 37 C.F.R.  
SECTION 1.97(e)**

*NOTE: A statement must state either: "(1) that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or (2) that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement." 37 C.F.R. Section 1.97(e).*

*NOTE: "Section 1.97(e) makes it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having a duty to disclose more than three months prior to the filing of the statement." Notice of January 9, 1992, 1135 O.G. 13-25, at 13. (emphasis added). Thus: "If an item of information is submitted within three months of being cited in a*

**CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))**

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

**FACSIMILE**

☐ transmitted by facsimile to the Patent and Trademark Office, (703) \_\_\_\_-\_\_\_\_.

Date: December 15, 2003

Signature

**Samuel J. Petuchowski**

(type or print name of person certifying)

communication from a foreign patent office in a counterpart foreign application, the certification can be properly made regardless of any individual's previous knowledge of the information." *Id.*, 1135 O.G. at 19.

NOTE: "The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Thus, for example, the certification of Section 1.97(e) does not preclude the use of the certification in an application by corporations whose practitioners have over the years reviewed thousands of patents and technical publications, even though they are unaware of the relevance of any one thereof to the application. Notice of January 9, 1992, 1135 O.G. 13-15, at 19.

NOTE: A copy of the foreign search report need not be submitted with the certification. Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: "The phrase 'after making reasonable inquiry' makes it clear that the individual making the certification has a duty to make reasonable inquiry regarding the facts that are being certified. The certification can be made by a registered practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A registered practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry. For example, if an inventor gave a publication to the attorney prosecuting an application with the intent that it be cited to the Office, the attorney should inquire as to when that inventor became aware of the publication and should not submit a certification under 37 C.F.R. 1.97(e)(2) to the Office until a satisfactory response is received. The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "Although it is recognized that an individual actually becomes aware of the information in the communication from a foreign patent office sometime after it was mailed, the mailing date of such a communication, if it occurs prior to a first awareness of the same information, would determine the date for filing of an information disclosure statement without a fee" in a certification procedure under Section 1.97(e). Notice of January 9, 1992, 1135 O.G. 13-25, at 19 (emphasis added).

NOTE: The mere absence of an item of information for a foreign patent office communication is not intended to represent an opportunity to delay the submission of a item known more than three months prior to the filing of an information disclosure statement to an individual having the duty of disclosure under Section 1.56. 62 Fed. Reg. 53,131, 53,150 (Oct. 10, 1997).

NOTE: "The certification under Section 1.97(e) should be made by a person who has knowledge of the facts being certified. The certification can be made by a practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry." Notice of January 9, 1992, 1135 O.G. 13-25 at 19.

NOTE: "The term counterpart foreign patent application means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application)." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." 37 C.F.R. Section 1.56(d) and

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) each inventor named in the application;

(2) each attorney or agent who prepares or prosecutes the application; and

(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. Section 1.56(c).

**IDENTIFICATION OF INFORMATION DISCLOSURE STATEMENT  
FOR WHICH THIS STATEMENT IS BEING MADE**

1. This statement is being made for the Information Disclosure Statement

☒ accompanying this statement.

☐ filed \_\_\_\_\_.

Date

**STATEMENT**

2. I, the person(s) signing below state:

☒ that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

*NOTE: The three month period starts from the mailing date of the foreign patent office communication. Notice of January 9, 1992, 1135 O.G. 13-25 at 19. The mailing date is the "date on the communication by the foreign patent office." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**OR**

☐ that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

*NOTE: "The time at which information 'was known to any individual designated in 37 C.F.R. 1.56(c)' is the time when the information was discovered in association with the application even if awareness of the materiality came later." Notice of April 20, 1992 (1138 O.G. 37-41, 40).*

**IDENTIFICATION OF PERSON(S) MAKING THIS STATEMENT**

3. The person making this statement is

*(check each applicable item)*

(a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

(b) ☐ a person who is substantively involved in the preparation or prosecution of the application, and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application (37 C.F.R. Section 1.56(c)) and who signs below.

**SIGNATURE OF PERSON MAKING STATEMENT**

*(type name of person who is signing)*

Address of person who is signing

(c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

- ☐ supplied by the inventor(s).
- ☐ supplied by an individual designated in Section 1.56(c).
- ☒ in the practitioner's file.



**SIGNATURE OF PRACTITIONER**

Reg. No. 37,910

Tel. No. (617) 443-9292

Customer No.:002101

Samuel J. Petuchowski  
*(type or print name of practitioner)*  
Bromberg & Sunstein LLP  
125 Summer Street  
Boston, MA 02110-1618